LabCoP ECHO Session
20 June 2024

Main Changes to the Revised SLIPTA Checklist V- 3

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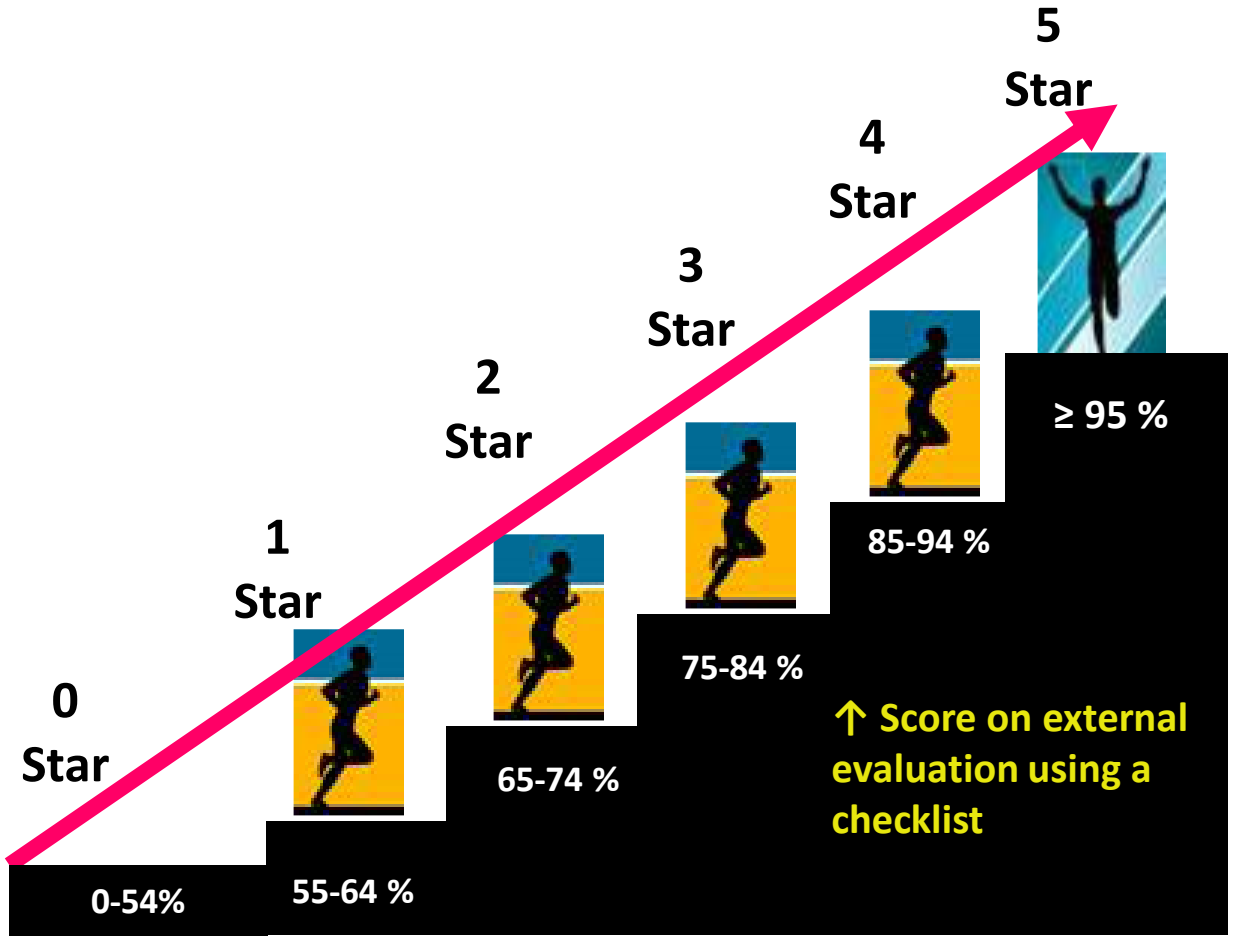
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA)

- A framework for improvement of laboratory quality system in developing countries to fulfill the ISO 15189 requirements in a stepwise process.
- Designed based on ISO 15189 Standards and the 12 QSEs of CLSI (QMS01-A4).
- The checklist is organized in 12 main sections and aggregate absolute **% scores** used for star rating.

SLIPTA Recognition – Star Levels



End Point

Accreditation

[National, Regional or International ABs]

Use of the SLIPTA Checklist

- Determine if a laboratory is providing **accurate** and **reliable** test results;
- Determine if the laboratory is **well-managed** and is adhering to **good laboratory practices (GLP)**;
- Identify **areas for improvement**;
- Audit report is used to generate **laboratory specific plans.**

Revision of SLIPTA

From Nov. 2011 – Aug. 2015

V-1 © 2011

Based on ISO 15189:2007

From Sept. 2015 – Dec. 2023

V-2 © 2015

Based on ISO 15189:2012

From Jan. 2024 –

V-3 © 2023

Based on ISO 15189:2022

Changes of SLIPTA Checklist V-3

- Aligned with the **new** 12 QSEs and ISO Clauses (4 – 8)
- The checklist promotes adoption of **process approach –** pre-examination, examination, post-examination and supporting areas
- Unlike the previous SLIPTA Checklist **Section 1.5**; Policy and SOPs are disbursed to various sections based on applicability,
- Questions are very clear and simplified to be user friendly
- Brings ease of evaluation of laboratory operations and QMS implementation,
  - ***Encourages smooth audit flow***

Changes of SLIPTA Checklist V-3 …

- The ***"Note"*** provided in each question describes **concepts**, **examples** and **methods** that can be considered by the laboratory when establishing, implementing and maintaining a QMS

SLIPTA Checklist V-3 consists of three parts

- **Part I: Laboratory Profile**
- **Part II: Laboratory Audits**
- **Part III: Summary of Audit Findings**

- The checklist is formatted into editable PDF and can be used as a soft copy, it can be completed as a form by typing in the grey blocks.
  - ***This would help to avoid transcriptional and calculation errors!***

Scoring with SLIPTA Checklist V-3

- For each question, the available options are
  - **Yes (Y),**
  - **Partial (P),**
  - **No (N),**
  - **Not Applicable (NA)**

- Each item has a point value of **2** or **3** based on relative importance and complexity
  - Items marked **(P)** will receive 1 (one) point
  - Items marked **(N)** receive 0 (zero) points.

Scoring of SLIPTA Checklist V - 3

Audit Score Sheet			
Section	**Audit score obtained**	**Total possible score**	
Section 1: Documents and Records		22	28
Section 2: Organisation and Leadership		26	14
Section 3: Personnel Management		34	22
Section 4: Customer Focus		24	10
Section 5: Equipment Management		38	35
Section 6: Assessments		24	15
Section 7: Supplier and Inventory Management		27	24
Section 8: Process Management		71	32
Section 9: Information Management		24	21
Section 10: Nonconforming Event Management		13	19
Section 11: Continual Improvement		07	12
Section 12: Facilities and Safety		57	43
TOTAL		367	275
Calculated percentage score obtained		%	

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 205 pts)	(206 – 240 pts)	(241 – 277 pts)	(278 – 314 pts)	(315 – 352 pts)	(353 – 367 pts)
< 55%	*55 – 64%*	*65 – 74%*	*75 – 84%*	*85 – 94%*	*≥95%*

Auditing using SLIPTA Checklist V - 3

Auditors must complete the SLIPTA checklist using the methods below:

- Review of laboratory documents and records
  - Observe laboratory operations
    - Ask questions (interview)
      - Follow a specimen through the laboratory
      - Confirm that test result(s) can be traced
      - Check EQA / proficiency testing results
      - Evaluate the quality and efficiency of supporting work areas

        (phlebotomy, data registration & reception, messengers, drivers, cleaners, IT, etc)
      - Discuss with clinicians

R O A D – assessment technique!

SLIPTA Checklist V-3 Questions

SECTION 01: DOCUMENT AND RECORDS

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field, you may also provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
1.1 Legal Entity Does the laboratory have documentation stating its legal identity? ***Note: Documentation could be in the form of a National Act, company registration certificate, license number or practice number, official letter from the Ministry of Health or equivalent institution to indicate that it belongs to the government.***		**Score** /2
ISO15189:2022 Clause 5.1		

SLIPTA Checklist V-3 Questions

1.10 Archived Patient Results Accessibility Is there an archiving system that allows for easy and timely retrieval of patient results as per the requirements of Section 9 of this checklist? ***Note: Records can be in any form or type of medium, providing they are readily accessible and protected from unauthorised alterations. Archived patient results must be easily, readily and completely retrievable within a timeframe consistent with patient care needs.***		**Score** 1 /2
ISO15189:2022 Clause 8.4		

SECTION 01: DOCUMENT AND RECORDS	12 **/22**

Audit Score Table

Section	Audit score obtained	Total possible score
Section 1: Documents and Records	12	22
Section 2: Organisation and Leadership	0	26
Section 3: Personnel Management	0	34
Section 4: Customer Focus	0	24
Section 5: Equipment Management	0	38
Section 6: Assessments	0	24
Section 7: Supplier and Inventory Management	0	27
Section 8: Process Management	0	71
Section 9: Information Management	0	24
Section 10: Nonconforming Event Management	0	13
Section 11: Continual Improvement	0	07
Section 12: Facilities and Safety	0	57
TOTAL	12	367
Calculated percentage score obtained		%

SLIPTA Audit Report

- **Completed SLIPTA checklist**
- **Nonconformity (NC) Table**

No	SLIPTA Checklist Question #	Nonconformity	Recommendation	ISO 15189:2022 Clause	Minor/ Major

Home take message!

- Some of the concepts are still kept in the SLIPTA Checklist V-3 to encourage and facilitate smooth establishment, implementation and maintenance of QMS
  E.g. - **Quality** Management System
  - Evidence for legal entity
  - Quality manual
  - Quality Officer or Manager, etc
- SLIPTA can now be effectively applied in POCT, diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion centers, etc
- Training and TA (mentorship) are the two fundamental plan to keep staffs and management engaged in all the processes.
- Audit report can be used as evidence-based-information for planning and follow up purposes!

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Guide on the transition roadmap and how countries can support this

Dr Samba Diallo
Portfolio Lead

Transition Plan for ISO15189:2022

- ISO 15189:2022 was released in December 2022, and ILAC provided deadline for the transition to be completed in December 2025
- Countries, Accrediting Body (AB), and laboratories shall work on this transition
- ASLM provide training and technical advice to country and to laboratory staffs to create awareness and help them to actively participate in the transition.
  - ASLM has been training laboratorians on ISO 15189:2022 standards (e.g. WAHO, Africa CDC, and GHSS,…)
  - ASLM has revised and released the SLIPTA Checklist-V3 (December 2023)
  - ASLM will train auditors to use SLIPTA Checklist V-3

Transition to use SLIPTA Checklist V-3 (2023)

- SLIPTA Checklist V-3 (2023) facilitate:
  - **Smooth transition** of the existing QMS based on ISO15189:2022 standards
  - The assessment of laboratory QMS
  - Identification of gaps that need attention
  - Development of a transition plan based on identified gaps
  - Monitoring of progress toward accreditation (Action Tracker)

Transition to use SLIPTA Checklist V-3 (2023)

ACTION TRACKER

SLIPTA Checklist V3 Clauses	Title	ISO 15189:2022 Clauses	Title	Comments	Notes	Existing Systems/ procedure reference	Action required Y/N?	Responsibility for action	Target completion date	Completion date

Support in the Expansion of SLIPTA

Countries (MoH/Lab Directorate):

- Designation of a national coordination mechanism
- Coordination of IPs and stakeholders
- Logistics support for training, audit and TA
- Use locally available auditor

Laboratories:

- Create synergy between IPs and stakeholders
- Training and awareness creation
- Effective and efficient implementation of QMS
- Aspire to achieve accreditation

Auditors:

- Continually improve competency in audits and QMS
- Voluntarily avail to audit laboratories

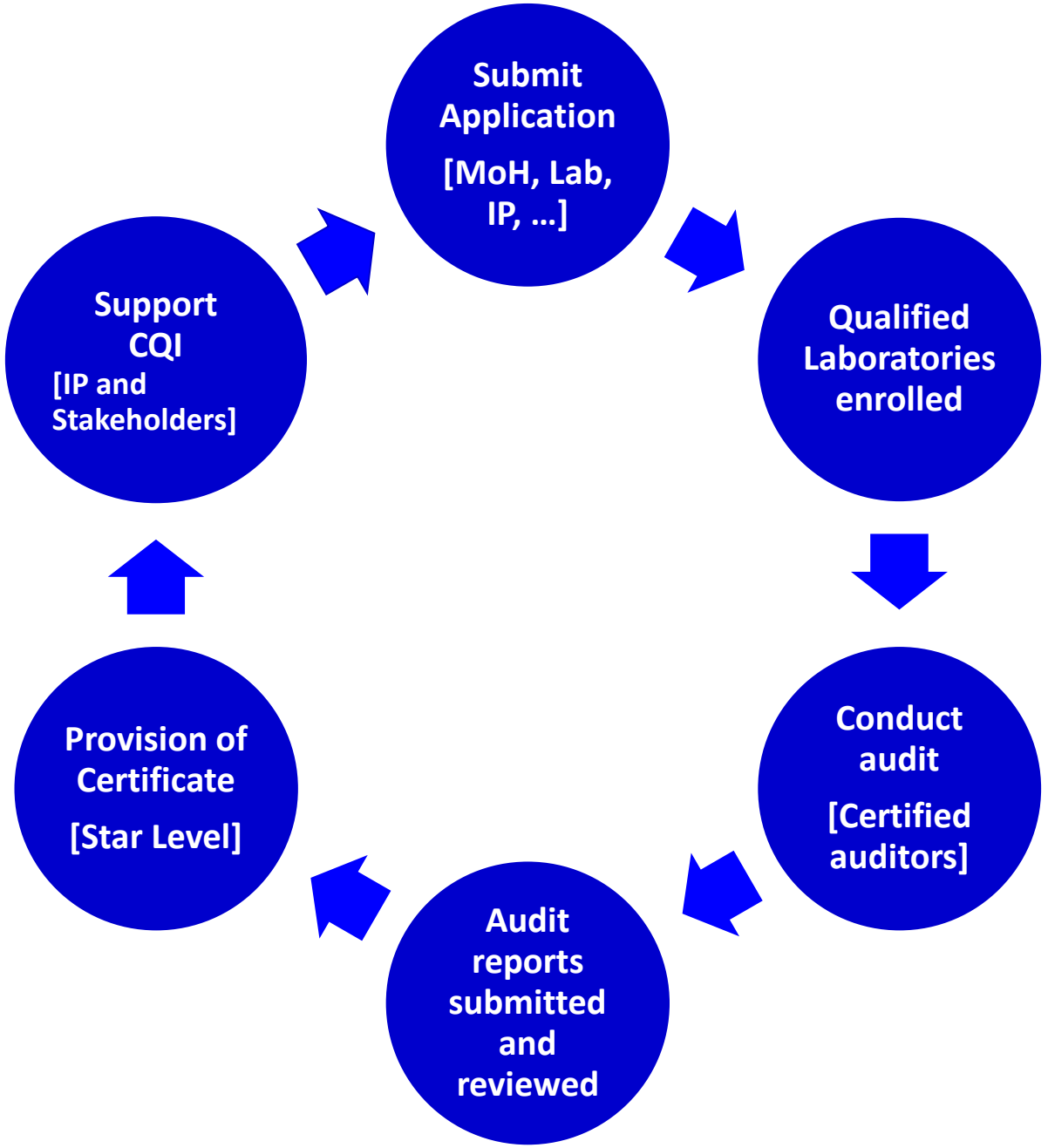
Country support for SLIPTA Checklist V3 implementation

- Commitment from all MoH, Lab directorate including laboratory professional
- Update country regulatory and laboratory governance documents (as needed)
- Get ASLM certified SLIPTA auditors trained on the SLIPTA Checklist V3
- Use SLIPTA checklist V3 to assess selected laboratories & monitor progress towards accreditation
- Enrol laboratories in the ASLM SLIPTA program (for assessment and TA)
- Communicate with the selected Accrediting Body (updated requirements and timelines)

SLIPTA Checklist V3 implementation at facility level

- Get commitment from all laboratory management and staffs
- Obtain a copy of ISO 15189:2022 standard and SLIPTA Checklist V3 (ASLM website)
- Get trained on the changes on both documents
- Conduct a self assessment using SLIPTA Checklist V3
- Develop a Transition Roadmap/Plan to adopt changes and new requirements
- Use SLIPTA Checklist V-3 to monitor progress towards accreditation
- Apply for ASLM SLIPTA recognition to obtain **SLIPTA Certificate**
- Communicate with Accrediting Body on updated requirements and timelines

Flowchart for SLIPTA audits



SLIPTA Application Form

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SLIPTA Application form for Enrollment

General Information

SLIPTA Eligibility for Enrollment Criteria

- Self-evaluation utilizing SLIPTA Checklist - Minimal score: **151 points** (55% compliance)
- Participation in proficiency testing (PT) schemes or inter-laboratory comparisons for all tests that were reported back to clinicians for at least one PT cycle in the past six months
- Routine run of quality controls for all test methods
- Evidence of internal audits conducted by the laboratory
- Documented Laboratory Quality Document

This form should be completed in full and returned with fees to:

African Society for Laboratory Medicine
Attention: SLIPTA Secretariat

Postal Address:
Nega City Mall, 8th Floor, Kirkos K/K, Kebele 08,
P. O. Box 5487
Addis Ababa, Ethiopia
Tel: +251 115 571026; +251 115 571021
Fax: +251 115 571030

The SLIPTA application fee is $200.00 per laboratory ($100.00USD application fee and additional $100.00 for report review, certificates and express mailing).

The application can be emailed to Mr Teferi Mekonen, SLIPTA Program Manager at tmekonen@aslm.org.

Possible timeline from Application to certificate receiving would be 2 months

Template certificate valid for 2 years

WHO AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation

Certificate of Recognition issued to:

"Insert Name of laboratory"

has been audited per the WHO AFRO SLIPTA Checklist and has met the requirements for the following star recognition level:

★ ★ ★

Valid: February 20, 2023 – February 19, 2025

The African Society for Laboratory Medicine accepts no liability for the laboratory testing conducted in facilities enrolled in SLIPTA.

The laboratory has achieved a star ranking on the SLIPTA Tier of Recognition of Laboratory Quality Management and is not a certificate of accreditation.

Ndlovu Nqobile
CEO - ASLM

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA ASLM

Period of validity

Availability of SLIPTA Information

The following information are available at the ASLM Resource Center:

https://aslm.org/what-we-do/#slipta

- ✓ SLIPTA Checklist V-3 in English, French and Portuguese
- ✓ Guidance on SLIPTA expansion
- ✓ SLIPTA Application form in three languages
- ✓ Updated list of ASLM certified SLIPTA auditors per country
- ✓ Map of SLIPTA audited laboratories per country

Acknowledgements

- WHO/AFRO
- Africa CDC
- US CDC/ CDC-Brazil
- ASLM Management
- Vijay Consulting
- ASLM Certified SLIPTA Auditors (English, French and Portuguese teams)
- NHLS team for piloting
- SLIPTA Revision Team
- ASLM LQMS TWG
- LabCop Team

Questions?
Comments?

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